Trevor Kerr

Thursday, 26 October 2006

Submission to
Inquiry into the Legislative responses to Recommendations of the Lockhart Review

Senators

My personal view is that the findings of the Lockhart Review should be enacted, as are the intentions of the private members Bills under consideration.

The Bill(s) must enshrine a regulatory body that is charged with ongoing and supportive oversight of scientific progress in this field. However, since future observations will guide the directions of research, it is impossible to predict, at this stage, what duties the regulatory body may be called on to perform on behalf of the public.

I believe, in summary, that regulation will be required in three areas, at least. Some aspects of these have been described in earlier submissions and presentations, and some have been barely hinted at by witnesses.

Therefore, future regulations will need to address

1. Accountability
2. Standard laboratory practices
3. Portability of data

Accountability
The simplest case for this need comes from the penalties prescribed in the Bill(s). It is easily conceived that, despite assurances that may have been given by witnesses, an individual Somatic Cell Nuclear Transfer (SCNT) preparation may be, inadvertently, allowed to proceed beyond the (arbitrary) 14-day stage. Some laboratories may police their procedures and staff for these kinds of errors, some may not. When mistakes occur, some laboratories may decide to conceal them and some may decide to disclose. Institutions that choose to stand on their own digs, and cry professional honour, need only be pointed toward the endeavours of Dr Hwang Woo-Suk. Considering the severe penalties, it would make sense for laboratories to collaborate in setting up procedures that minimise risk of breach, using a quality framework that learns from mistakes and near misses. It would be surprising to find that Australian institutions have not dispatched personnel to find out, first hand, what went wrong in Dr Hwang's laboratory. It would be alarming if Australian laboratory practices have not been examined to prove that errors and fraud can be detected by audit, in the light of the above.

It is undeniable that opponents of the research will continue to examine processes in detail. Researchers must be protected from charges that they do not have respect for human life. Scientists who refer to the "handling of embryos", as part of their work, could be open to challenge as to their beliefs and personal ethical standards. So, if a laboratory's practices are examined by external and independent audit, the laboratory management should be accountable for shortfalls. It should not be up to individual institutes to set their own standards, in, say, their diligence in making sure incubations are terminated at 14 days. Neither should a collaboration of institutes, through a self-directed process that's sponsored by government, be allowed to rubber-stamp procedures.

I believe one of the witnesses stated that he was, at the same time, head of the HREC of a prominent institution and party to another agency that is sponsored by a pharmaceutical company. (This important linkage is not apparent at

http://www.alfredresearch.org/ethics/ecommitteemem.htm). For public confidence, perhaps a new kind of oversight is required, one that is totally disconnected from industry and the institutes, and one that is empowered to declare the financial interests of its members. I would encourage Senators to have a look at the website of the UK's Human Genetics Commission, as a rare example of full disclosure and public accountability. It should not be up to an investigative journalist to expose a renowned professor's interests in companies; that information should be provided freely, published and amenable to public inquiry.

Standard laboratory practices

I believe it will be necessary that laboratories have ready access to pools, or banks, of donated human ova, in order to perform SCNT work in an efficient manner. Basic laboratory procedures require variable approaches and refinement of techniques. When a procedure is established, new workers will need to be trained in the techniques. It is obvious, then, that at various times, laboratory work will proceed effectively if the workers can draw on their own stocks. For example, a stage in development may call for several ova to be processed at the same time. If the laboratory had a bank of 100 or so ova in the freezer, these could be used without further delay.

Moreover, it may turn out that unique substances are produced by dividing cells, and these may be extracted and used to stimulate or enhance specific stages to a desired endpoint. If that turns out to be, then that will be another reason to have stocks of ova on hand. Again, these ova would be anonymous as to their maternal origin.

Most of the ova used in procedures, in the early stages of development of techniques, will be consumed without any intention to discover new therapies based solely on those particular lines. There is, therefore, no need for a chain of evidence linking the ova back to their sources. Many ova could, and should, be completely anonymous to the laboratory. Procedures can be envisaged where each ovum is de-identified at the point of collection, so that it would be impossible, short of extensive retro-spective analysis, to establish identity of any subsequent genetic material derived from that ovum. However, an irreversible de-identification procedure would kill any chance of recovery of identity. If, for example, an ovum appeared to have unqiue properties that enhanced SCNT research in some way, it may be desirable to seek to obtain more ova from the donor, if possible.

It seems, then, that the regulating body needs to consider how it would both de-identify all ova, and allow re-identification, through the agency of a trusted broker.

Portability of data

In at least two scenarios, derived data will have to be conserved in ways that preclude the possibility of error.

When cells are manipulated for the purpose of finding a therapy for a specific individual patient, the labelling and intra-laboratory tracking prodecures must be faultless. It is possible that the standards of record-keeping may need to be higher than that in IVF laboratories, or that in neonatal nurseries, to avoid mix-up.

The second occasion will arise when material derived from original research is handed over, through sale or otherwise, to another body for further work. If the research done in Australian laboratories is to have any value for transactions, the material must be able to be verified as to its pedigree (genetic origins) and provenance (where it has been, and who has handled it). Commercial transactions, where millions of dollars are at stake, will demand foolproof records.

In conclusion, I believe strongly that the overseeing body must establish and maintain a register that is capable of tracking material specified for use in SCNT procedures, from point of origin or collection. The register should record transactions, and hold keys to data that authenticates and verifies the pedigrees and provenance of material. In the case of an ovum that has been donated for use in routine process, the register will de-identify the material before it is licensed for use. The register will recognise the stringent needs for documentation that will allow value to be added to material, so it can be made available for further research and development.

Finally, the activities of the regulating body must be fully funded by the public. Senators, you must take notice of the outcomes when authorising bodies, such as the USA's FDA, are forced to accept funding from industry. In my view, such compromise is betrayal of the public trust. One incident, like the scandal created over Vioxx, would be enough to set back Australian research by years. The business cases for liberalised research are compelling, but they must not overrule the imperative for a rigorous ethical framework. To this end, you must allow for, if not explore, the ways and means whereby first-class information technology can assist the management of SCNT research. Please, also, consider the work the Australian Law Reform Commission has done on genetic privacy, and is doing on information privacy.

[This commentary was stimulated by the excellent hearing in Melbourne, Oct. 24th.]

Yours sincerely,

Trevor Kerr FRCPA, MB.BS, B.Sc